The following corrections or additions to the January 15, 1998 list were made in March, 1998

New Approvals

ANADA Number: 200-242
Pioneer Product: 141-059
Trade Name : BMDTM -25, 30, 40, 50, 60 or 75; and
Aureomycin-50, 70, 80, 90 or 100
Ingredients: Bacitracin methylene disalicylate
Chlortetracycline calcium complex equivalent to Chlortetracycline HCl
Sponsor: Hoffmann-La Roche, Inc.
Approval Date: 01/16/98
Status: Over-the-counter
Route: Oral
Species: Porcine
Drug Form: Type A medicated articles to make Type C medicated feeds
Concentration: Bacitracin MD: 25, 30, 50, 60, or 75 g/lb
Chlortetracycline: 50, 70, 80, 90, or 100 g/lb
Indications: Bacitracin MD: For increased rate of weight gain and improved feed efficiency
Chlortetracycline: For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis,* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.
Tolerance: 21CFR 556.70: Bacitracin: 0.5 ppm negligible residue in uncooked edible tissues of swine.
21CFR 556.150: Chlortetracycline: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal: Zero days.

This ANADA provides for the combined use of two approved Type A medicated articles in Type C medicated feeds, rather than a premix incorporating both of these compounds.

21CFR 558.76 and 558.128

NADA Number: 141-067
Trade Name : Oxyglobin
Ingredients: Hemoglobin glutamer-200 (bovine)
Sponsor: Biopure Corporation
Approval Date: 01/28/98
Status: Prescription only
Route: Intravenous
Species: Canine
Drug Form: Liquid (solution)
Concentration: 13 g/dL
Indications: For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia for at least 24 hours, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

Patent Number:	5,084,558	Expiration date	01/28/2009
	5,296,465		03/22/2011
	5,618,919		04/18/2014

Exclusivity: 5 years

21CFR 522.1125 and 510.600

NADA Number: 141-029
Trade Name : Percorten TM -V
Ingredients: Desoxycorticosterone pivalate
Sponsor: Novartis Animal Health US, Inc.
Approval Date: 01/12/98
Status: Prescription only
Route: Intramuscular
Species: Canine
Drug Form: Liquid (suspension)
Concentration: 25 mg/mL
Indications: For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.
Exclusivity: 5 years

21CFR 522.535

NADA Number: 141-069
Trade Name : First GuardTM Sterile Powder
Ingredients: Colistimethate sodium
Sponsor: Alpharma, Inc.
Approval Date: 01/13/98
Status: Prescription only
Route: Subcutaneous
Species: Avian (1 to 3-day old chickens; not for use in laying hens producing eggs for human consumption)
Drug Form: Powder
Concentration: 133 mg colistin activity/mL (reconstituted vial solution)
Indications: For the control of early mortality associated with *E. coli* organisms susceptible to colistin in 1 to 3-day old chickens.
Tolerance: Not required
Withdrawal: Zero days
Exclusivity: 5 years

21CFR 522.468 and 556.167

NADA Number: 140-843
Trade Name : Monteban(Elanco Animal Health)
Flavomycin (Hoechst Roussel Vet)
3-Nitro (Alpharma)
Ingredients: Narasin
Bambermycins
Roxarsone
Sponsor: Hoechst Roussel Vet
Approval Date: 03/18/98
Status: Over-the-counter

Route: Oral
Species: Avian (broiler chickens)
Drug Form: Type A medicated articles to make Type C medicated feeds
Concentration: Narasin: 45 g/lb
Bambermycins: 4 and 10 g/lb
Roxarsone: 45.4, 90, and 227 g/lb
Indications: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.
Tolerance: 21CFR 556.428: Narasin: a tolerance for narasin residues in chickens is not needed. The safe concentrations for total narasin residues in uncooked edible chicken tissues are: 0.6 ppm in muscle, 1.8 ppm in liver, 1.2 ppm in skin and fat. Bambermycins has a no tolerance clearance.
21CFR 556.60: Arsenic (from roxarsone): 0.5 ppm in muscle and 2 ppm in edible by-products with liver as the target tissue.
Withdrawal: 5 days
Exclusivity: 3 years

This NADA provides for the combined use of three approved Type A medicated articles in Type C medicated feeds, rather than a premix incorporating all three of these compounds.

21CFR 558.363, 558.95, and 558.366

NADA Number: 141-099
Trade Name : Cydectin (moxidectin) 0.5% Pour-On for Cattle
Ingredients: Moxidectin
Sponsor: Fort Dodge Animal Health
Approval Date: 01/28/98
Status: Over-the-counter
Route: Topical
Species: Bovine (beef cattle and non-lactating dairy cattle)
Drug Form: Liquid (solution)
Concentration: 5 mg/mL
Indications: For the treatment and control of the following internal [adult and fourth stage larvae (L4)] and external parasites of cattle.
Gastrointestinal roundworms *Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult), *Trichostrongylus axei* (adult and L4), *Trichostrongylus colubriformis* (adult), *Cooperia oncophora* (adult), *Cooperia punctata* (adult), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult), *Nematodirus helvetianus* (adult).
Lungworm *Dictyocaulus viviparus* (adult and L4).
Cattle Grubs *Hypoderma bovis, Hypoderma lineatum*
Mites *Chorioptes bovis, Psoroptes ovis* (*Psoroptes communis* var. *bovis*).
Lice *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Damalinia bovis*
Horn flies *Haematobia irritans*
To control infections and to protect from reinfection from *Ostertagia ostertagi* for 28 days after treatment and from *Dictyocaulus viviparus* for 42 days after treatment.
Tolerance: 21CFR 556.426: an acceptable daily intake (ADI) of 4 micrograms/kg/day in tissue is established. A tolerance is established for parent moxidectin in edible tissues of cattle of 50 ppb in muscle and 200 ppb in liver.
Withdrawal: Not required.

Patent No.: 4916154 Expiration date: 04/10/2007
Exclusivity: 3 years

21CFR 524.1451 and 556.426

Supplemental Approvals

NADA Number: 055-099
Trade Name : Clavamox Tabs
Ingredients: Amoxicillin trihydrate, clavulanate potassium
Sponsor: Pfizer, Inc.
Approval Date: 12/23/97
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablets
Concentration: 62.5, 125, 250, and 375 mg/tablet
Indications: For the treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: [[beta]]-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*.
For the treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

Patent Number:	4367175	Expiration date	01/04/2000
	4441609		04/10/2001
	4525352		06/25/2002
	4529720		07/16/2002
	4560552		12/24/2002

Exclusivity: 3 years

This supplemental application provides for the additional claim against canine periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

21CFR 520.88g

NADA Number: 055-101
Trade Name : Clavamox Drops
Ingredients: Amoxicillin trihydrate, clavulanate potassium
Sponsor: Pfizer, Inc.
Approval Date: 12/23/97
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Liquid (suspension)
Concentration: 50 mg amoxicillin and 12.5 mg clavulanic acid/mL
Indications: For the treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: [[beta]]-lactamase-producing *Staphylococcus aureus*, non-beta-lactamase-producing *Staphylococcus aureus*, *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*.

For the treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

Patent No.:	4367175	Expiration date	01/04/2000
	4525352		06/25/2002
	4529720		07/16/2002
	4560552		12/24/2002

Exclusivity: 3 years

This supplemental application provides for the additional claim against canine periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

21CFR 520.88h

NADA Number: 041-061
Trade Name : Mecadox10 Premix
Ingredients: Carbadox
Sponsor: Pfizer, Inc.
Approval Date: 01/30/98
Status: Over-the-counter
Route: Oral
Species: Porcine
Drug Form: Type A medicated article
Concentration: 10-25 g/ton and 50 g/ton in Type C medicated feeds.
Indications: For the control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery), bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); for increased rate of weight gain and improvement of feed efficiency.
Tolerance: 21CFR 556.100: 30 ppb in swine liver is established for residues of quinoxaline-2-carboxylic acid (marker residue).
Paten Number: 4211781 Expiration Date: 07/08/1997
Exclusivity: 3 years

This supplemental application provides for the codification of a revised finite tolerance for residues of carbadox in edible tissues of swine.

21CFR 556.100

NADA Number: 049-287
Trade Name : Pfichlor Type A Medicated Article
Ingredients: Chlortetracycline calcium complex
Sponsor: Hoffmann-La Roche, Inc.
Approval Date: 01/27/98
Status: Over-the-counter
Route: Oral
Species: Bovine (cattle, calves), ovine, porcine, avian (chickens, turkeys)
Drug Form: Type A medicated article
Concentration: 50, 70, and 100 g/lb of chlortetracycline HCl

Indications: Chickens
10-50 g/ton: for increased rate of weight gain and improved feed efficiency in broiler/fryer chickens.
100-200 g/ton: for the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.
200-400 g/ton: for the control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.
Do not feed to chickens producing eggs for human consumption.
500 g/ton: for the reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline. Do not feed to chickens producing eggs for human consumption.
Turkeys
10-50 g/ton: for an increased rate of weight gain and improved feed efficiency.
200 g/ton: for the control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.
400 g/ton: for the control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline. Turkey poults not over 4 weeks of age: for the reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.
25 mg/lb body weight daily: for the control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.
Do not feed to turkeys producing eggs for human consumption.
Swine
10-50 g/ton: growing swine: for an increased rate of weight gain and improved feed efficiency.
50-100 g/ton: for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci* susceptible to chlortetracycline.
400 g/ton: Breeding swine: for the control of leptospirosis (reducing the instances of abortion and shedding of leptospires) caused by *Leptospira pomona* susceptible to chlortetracycline.
110 mg/lb body weight daily: for the treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.
Sheep
20-50 g/ton: Growing sheep: for an increased rate of weight gain and improved feed efficiency.
80 mg/head/day: Breeding sheep: for reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline.
Calves, beef cattle, and non-lactating dairy cattle
0.1 mg/lb body weight daily: Calves (up to 250 lbs): for an increased rate of weight gain and improved feed efficiency.
25-70 mg/head/day: Calves (250-400 lbs): for an increased rate of weight gain and improved feed efficiency.
70 mg/head/day: Growing cattle (over 400 lbs): for an increased rate of weight gain, improved feed efficiency and reduction of liver condemnation due to liver abscesses.
Do not use in calves to be processed for veal.
350 mg/head/day: Cattle: for the control of bacterial pneumonia associated with shipping fever complex caused by Pasteurella spp. susceptible to chlortetracycline.
350 mg/head/day: Beef cattle (under 700 lbs): for the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.
0.5 mg/lb/day: Beef cattle (over 700 lbs): for the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.
10 mg/lb body weight/day: Calves, beef, and non-lactating dairy cattle: for the treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

Tolerance: 21CFR 556.150: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal: Chickens at 10-50 g/ton, 100-200 g/ton, and 200-400 g/ton: zero days.
Chickens at 500 g/ton: 24 hours.
Turkeys, swine, and sheep: zero days.
Calves and growing cattle at 0.1 mg/lb body weight/day, 25-70 mg/head/day, and 70 mg/head/day: zero days. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.
Cattle at 350 mg/head/day and 0.5 mg/lb/day: 48 hours.
Calves, beef, and non-lactating dairy cattle at 10 mg/lb body weight/day: 10 days.

This supplemental application provides for compliance with the conclusions of the National Academy of Science/National Research Council (NAS/NRC) evaluation of Pfichlor Type A Medicated Articles (chlortetracycline calcium complex equivalent to chlortetracycline HCl).

21CFR 558.128

NADA Number: 100-901
Trade Name : Pfichlor 100S Milk Replacer Type A Medicated Article
Ingredients: Chlortetracycline calcium complex
Sponsor: Hoffmann-La Roche, Inc.
Approval Date: 01/27/98
Status: Over-the-counter
Route: Oral
Species: Bovine (calves)
Drug Form: Type A medicated article
Concentration: 100 g/lb chlortetracycline HCl
Indications: 0.1 mg/lb body weight daily: Calves (up to 250 lbs): for an increased rate of body weight gain and improved feed efficiency.
25-70 mg/head/day: Calves (250-400 lbs): for an increased rate of weight gain and improved feed efficiency.
10 mg/lb body weight daily: Calves: for the treatment of bacterial enteritis caused by *Escherichia coli*.
Tolerance: 21CFR 556.150: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.
Withdrawal: Calves at 0.1 mg/lb daily and 25-70 mg/head/day: zero days.
Calves at 10 mg/lb body weight daily: 10 days.
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

This supplemental application provides for compliance with the conclusions of the National Academy of Science/National Research Council (NAS/NRC) evaluation of Pfichlor 100S Milk Replacer Type A Medicated Articles (chlortetracycline calcium complex equivalent to chlortetracycline HCl).

21CFR 558.128

New Sponsor

Biopure Corp., 11 Hurley Street, Cambridge, MA 02141. Drug labeler code: 063075

Change of Sponsor's Address

Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067. Drug labeler code: 063271

Update of Patent Information

NADA 140-988: IVOMEC, SR Bolus for Cattle

Patent Number	Expiration Date	Patent Number	Expiration Date
4,199,569	10/03/1997	4,966,767	10/30/2007
4,327,725	11/23/2000	5,000,957	06/17/2003
4,595,583	03/19/2004	5,122,128	03/15/2010
4,684,524	06/17/2003	5,206,024	04/27/2010
4,692,336	06/17/2003	5,223,266	06/29/2010
4,704,118	08/16/2005	5,229,133	07/20/2010
4,717,568	05/01/2005	5,368,863	06/29/2010
4,717,718	06/17/2003	5,417,976	04/27/2010
4,729,793	03/08/2005	5,431,919	06/23/2013
4,772,474	06/12/2003	5,474,785	07/20/2010
4,844,984	06/17/2003	5,607,696	02/10/2015
4,927,633	06/17/2003		

Suitability Petition Action

Number.: 98P-0159/CP1
Sponsor: Phoenix Scientific, Inc.
Petition: Request permission to file an ANADA for a generic Ivermectin Chewable Tablet which differs from the pioneer product, Heartgard-30,, Merial Limited NADA 140-886 by the following characteristics:
Ivermectin generic is a compressed chewable tablet and Heartgard is an `extruded' chewable tablet.
Action: Filed on 03/11/98.